OFFICE OF ACQUISITIONS
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02AT67007-C16

Amendment No.: 2

Date of Issuance: 03/28/2016

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offerors remains unchanged: 2:00PM, April 11, 2016.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERORS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

This Amendment revises the RFP as stated below:

The purpose of this amendment is to:
To post the answers to the inquiries that have been submitted for response.
THE DUE DATE OF THE PROPOSAL REMAINS UNCHANGED AT 2:00PM EASTERN TIME (EDT), MONDAY, April11, 2016.

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The following questions have been submitted to the NCI OA for response. The answers to these questions are provided below.

1. Question: Is there is a page limitation for the technical proposal and for the appendices (for resumes, SOPs, and other sample documents)? [Possible omission to] General Instructions, page 31.
Answer: The page limit requirement is 125 pages plus appendices/attachments.

2. Question: How many site visits does NCCIH anticipate for the first year of the contract, and then for each option year? Similarly, does NCCIH anticipate there will be more multi-site than single-site visits?
Answer: We are currently conducting approximately 70 site visits/year under this contract. Our current grant profile includes a mix of single and multi-site studies. The multi-site studies that are funded by NCCIH rarely involve more than 1-2 additional sites. While we do not anticipate significant changes to this profile during the period of performance, NCCIH funds investigator-initiated grants and therefore the specific locations and number of funded studies will vary.

3. Questions: How many international site visits are anticipated for each year of the contract? (See SOW/Attachment 3, page 7 of 17.)
Answer: NCCIH does not currently have a large international clinical studies portfolio. We anticipate that there will be <5 visits per year, however, NCCIH funds investigator-initiated grants and therefore the specific locations and number of funded studies will vary.

4. Question: What will be the frequency of Data Safety and Monitoring Board (DSMB) and other meeting support per contract year? (See SOW/Attachment 3, page 13 of 17.)

Answer: It is anticipated that there will be support requested for <6 DSMB and other meetings per each contract year.

5. After Section M, the bookmarks in the Adobe PDF file of the RFP do not match the contents of the rest of the RFP. For example, the bookmarks include the PHS SBIR Solicitation for Contract Proposals. Can NCCIH please confirm that the bookmarks after Section M are not meant to be part of this RFP and that they should be ignored?

Answer: That is correct, please ignore the bookmarks after Section M, 6. Past Performance Factor. These bookmarks reference other solicitation and were erroneously inserted by the Document Generation System (DGS).

6. Attachment 3, Item 2.a on Page 6 notes NCCIH will provide the number, frequency and intensity of routine clinical site monitoring visits will be determined by NCCIH on a protocol-specific basis commensurate with the anticipated level of protocol risk and characteristics of the individual participating clinical sites. For budgeting purposes, can NCCIH provide uniform cost assumptions or historical data around the anticipated number of annual routine site monitoring visits?

Answer: We are currently conducting approximately 70 site visits/year under this contract. While we do not anticipate significant changes to this profile during the period of performance, NCCIH funds investigator-initiated grants and therefore the specific locations and number of funded studies will vary.

7. Attachment 3, Item 3.a on Page 7 notes the Contractor will provide a variety of clinical site visits. For budgeting purposes and cost realism, can NCCIH provide uniform cost assumptions or historical data around the anticipated number of specialized site monitoring visits including site initiation visits, site close-out visits, specialized pharmacy visits, specialized regulatory review visits, specialized database review visits, and remedial or "for cause" visits?

Answer: Our historical site visit information is as follows:
Year 1 Year 2 Year 3 Year 4 Year 5 (Q1+Q2)
Initiation 14 21 30 12 8
Interim 7 21 31 44 16
Initiation/Interim 3 1 1
Interim/Closeout 1 3 3 3
Closeout 4 4 1 11 4
Ad Hoc 3 4 8 2

Totals: 32 50 74 70 34

8. What is the expected total number and type of site visits per year of this contract?

Answer: We are currently conducting approximately 70 site visits/year under this contract. While we do not anticipate significant changes to this profile during the period of performance, NCCIH funds investigator-initiated grants and therefore the specific locations and number of funded studies will vary.

9. What is the total number and type of visits (e.g. initiation, routine monitoring, specialized monitoring, or site closeout visit) that have been conducted in the previous five years?
Answer: Our historical site visit information is as follows:

Year 1 Year 2 Year 3 Year 4 Year 5 (Q1+Q2)
Initiation 14 21 30 12 8
Interim 7 21 31 44 16
Initiation/Interim 3 1 1
Interim/Closeout 1 3 3 3
Closeout 4 4 1 11 4
Ad Hoc 3 4 8 2

Totals: 32 50 74 70 34

10. What is the allowable page limit for submitting a response?
a. For the Technical Proposal

Answer: The page limit requirement is 125 pages plus appendices/attachments.

b. Are the title page, table of contents, CV's , Appendices and SOPs included/excluded from the total page #?

Answer: No. The above would be considered an appendix or attachment; these are in addition to the 125 page limit.

11. There is a link , that was issued in the RFP dated 03/11/2016
a. NCCIH Policies and Guidelines http://nccih.nih.gov/research/policies/index.htm-
It does not appear to be working , is there an alternate link?

Answer: The link has been repaired.

c. The web site was last updated in 02/2015 nearly a year before the RFP was issued. -

Answer: No website was created specifically for the RFP. All NCCIH links are provided for reference only.

12. Clinical Site Monitoring
a. Will all monitoring be "on site" or will there be "remote/off site" monitoring included ?

Answer: All monitoring will be "on site".

13. Attachment 3, Statement of Work, Page 13 (of 17) F. Other Technical and Administrative Support, 1.a. - please confirm if the Contractor will only schedule and arrange transportation and lodging, and meeting room facilities OR will the Contractor also pay for transportation, lodging and meeting room facility rental costs?

Answer: The resultant Contractor will be responsible for arranging and paying for all transportation, lodging and meeting room facility rental costs required to successfully complete the Statement of Work. Transportation, lodging and meeting room facility rental costs will be an allowable cost and the resultant Contractor will be permitted to invoice for these expenses.

14. Question: Is the current clinicaltrials.gov representation of studies an accurate representation of the number of active studies and geographical location of studies anticipated for the contract period of performance? (61 North America and 1 South America (Peru) currently).

Answer: Not all studies that are currently being monitored are listed in clinicaltrials.gov, and not all studies listed in clinicaltrials.gov are currently monitored. However, the number of studies and locations listed provides a good representation of the current monitoring portfolio. While we do not anticipate significant changes to this profile during the period of performance, NCCIH funds investigator-initiated grants and therefore the specific locations and number of funded studies will vary.

15. Are the participating sites utilizing centralized electronic data and regulatory document management systems allowing for any level of remote/off-site monitoring? If yes, what percentage of protocols are?

Answer: We currently do not support remote/off-site monitoring and do not anticipate that this will change.

-END OF AMENDMENT-